

REMARKS

The pending Office Action addresses and rejects claims 1-34. Reconsideration is respectfully requested in view of the foregoing remarks and amendments presented.

Amendments to the Specification

Paragraphs [0009], [0015], [0018], [0034], and [0039] of the published application have been amended as indicated above. The amendments correct typographical errors to recite 4,6-dioxoheptanoic acid. Support for these amendments can be found in Provisional Application No. 60/462,937 upon which the instant case claims priority, for example at page 5, lines 7-9. No new matter is added.

Amendments to the Claims

Claim 25 has been amended to correct a typographical error and to recite 4,6-dioxoheptanoic acid. Support for this amendment can be found, for example, at page 5, lines 7-9 of Provisional Application No. 60/462,937 upon which the instant case claims priority. Claim 26 has been amended to recite “a duration that is equal to or greater than about 15 minutes” instead of “a duration of at least about 15 minutes.” No new matter is added.

Rejections Pursuant to 35 U.S.C. §112

Claims 16, 20, 22, and 24-26

The Examiner rejects claims 16, 20, 22, and 24-26 pursuant to 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 25 has been amended as indicated above, thereby obviating the bases for the Examiner’s rejection. Applicant respectfully disagrees that claims 16, 20, 22, 24, and 26 are indefinite.

Claims 16, 24, and 26

Regarding claim 16, the Examiner asserts that “[i]t is unclear as to whether Applicant desires the limitation to be about 25, which could be 24, or greater than 25, which could not be less than 25, as about 25 suggests.” However, Applicant has used clear language that includes both of the Examiner’s interpretations of claim 16. Claim 16 clearly recites a temperature that is either equal to about 25° C or greater than about 25° C. Alternative expressions using the word “or” are acceptable and not in violation of §112, second paragraph. (See MPEP 2173(h)(II)). Furthermore, for a claim such as claim 16 where the claim’s language and scope are clear, breadth of a claim does not equate with indefiniteness under §112, second paragraph. (See MPEP 2173.04).

Claim 24 uses language similar to claim 16, and claim 26 has been amended as indicated above to include language similar to claim 16. Accordingly, claims 24 and 26 are not indefinite at least for the same reasons as for claim 16.

Claims 20 and 22

The Examiner asserts that the terms “substantially destroy” and “substantially remove” in claims 20 and 22, respectively, are not defined in the specification. However, use of the word “substantially” does not make a claim indefinite. (See MPEP 2173.05(b)(D)). If a person of ordinary skill in the art would know what was meant by the limitation including the word “substantially,” then the claim is definite. (See *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988)). A person of ordinary skill in the art would know what was meant by “substantially destroy the malignant cells” and “substantially remove hair” as procedures involving destruction of malignant cells and removal of hair are common procedures having understood end results. Accordingly, for at least these reasons, claims 20 and 22 are not indefinite.

Claims 1, 23, and 24

The Examiner rejects claims 1, 23, and 24 pursuant to 35 U.S.C. §112, first paragraph as not reasonably providing enablement for all chemical inhibitors. Applicant respectfully disagrees. Claims 23 and 24 do not claim all chemical inhibitors. As clearly stated in claim 23 (upon which claim 24 depends), the method includes applying chemical inhibitors *that prevent metabolism of the*

pre-photosensitizing agent in epithelial tissue surrounding the targeted treatment site. A person skilled in the art would thus be able to select an appropriate chemical inhibitor, including but not limited to those disclosed in claim 25. For example, Applicant states in paragraph [0034] of the published application that “[a] variety of chemical inhibitors can be used with the method of the present invention, but the chemical inhibitor should be effective to inhibit metabolism of a pre-photosensitizing agent, such as a porphyrin precursor, into a photosensitizing agent, such as a porphyrin.” Accordingly, for at least these reasons, claims 1, 23, and 24 are enabling.

Rejections Pursuant to 35 U.S.C. §103

Claims 1-19 and 22

The Examiner rejects claims 1-19 and 22 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,050,990 (“Tankovich”) in view of U.S. Patent No. 5,709,654 (“Klatz”). Applicant respectfully disagrees.

Independent claim 1 recites a method that includes administering a pre-photosensitizing agent to a targeted treatment site and preventing metabolism of the pre-photosensitizing agent in epithelial tissue surrounding the targeted treatment site, while allowing the pre-photosensitizing agent to metabolize into a photosensitizing agent in tissue at the targeted treatment site. The method also includes irradiating the treatment site to activate the photosensitizing agent at the targeted treatment site, wherein the epithelial tissue surrounding the targeted treatment site is substantially unaffected.

Tankovich in view of Klatz does not teach or suggest *preventing metabolism of the pre-photosensitizing agent* in epithelial tissue surrounding the targeted treatment site *while allowing the pre-photosensitizing agent to metabolize* into a photosensitizing agent in tissue at the targeted treatment site. The Examiner concedes that Tankovich does not teach this recitation of claim 1 and relies on Klatz to remedy the deficiency of Tankovich.

1. Klatz Does Not Remedy The Deficiencies Of Tankovich

Klatz does not remedy the deficiencies of Tankovich because Klatz only discloses general inhibition of organ metabolism through cooling of entire organs for preservation and/or resuscitation purposes. Klatz does not teach or suggest preventing metabolism surrounding a targeted treatment site *while allowing metabolism in tissue at the targeted treatment site*. No mention is made whatsoever regarding any sort of selective or spatially significant cooling of tissue. Indeed, cooling of tissue in Klatz must be non-selective and spatially insignificant because an entire organ must be cooled to properly preserve it. Furthermore, there is no mention of applying ALA or any other pre-photosensitizing agent in Klatz whose metabolism can be selectively prevented and allowed. Tankovich also does not provide such a teaching, as indicated below. Thus, neither Klatz nor Tankovich teaches or suggests preventing metabolism of the pre-photosensitizing agent in epithelial tissue surrounding the targeted treatment site while allowing the pre-photosensitizing agent to metabolize into a photosensitizing agent in tissue at the targeted treatment site.

2. There Is No Reason, Suggestion or Motivation To Combine Klatz With Tankovich

A prima facie case of obviousness can only be established by meeting three criteria outlined in MPEP §2133: "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." Without conceding that Klatz teaches preventing metabolism as recited in claim 1 or that there would be a reasonable expectation of success in combining the references, there is no reason, suggestion, or motivation to combine Tankovich with Klatz.

Tankovich in view of Klatz cannot render claim 1 obvious because there is no reason, suggestion, or motivation to combine Klatz with Tankovich because the fields of the references are completely different. Tankovich is directed to inhibiting hair growth and related skin treatments. Klatz is drawn to cooling tissue, and in particular to preserving and/or resuscitating organs. A person skilled in the art, and looking for techniques of preventing hair growth or otherwise selectively treating skin, would have no reason or motivation whatsoever to look to literature

teaching temperature control of internal organs for preservational purposes: the fields are different; the medical procedures are different; and the results are different. Furthermore, Tankovich does not teach or suggest cooling tissue while using ALA, so a person skilled in the art would not look to Klatz (or any other reference) for temperature control of tissue treated with ALA. Accordingly, since there is no reason, suggestion, or motivation to combine the cited art, a prima facie case of obviousness cannot be established against claim 1.

3. Tankovich Does Not Teach Or Suggest Claim 1

Regardless of what Klatz teaches, the Office Action's contention that Tankovich teaches preventing metabolism of a pre-photosensitizing agent is not correct. Such an interpretation of Tankovich confuses the reference's teachings and combines completely unrelated methods in a way that they would not, and could not, be combined. Method Nos. 8 and 22 of Tankovich would not be combined and, in fact, together would not have a reasonable expectation of success.

At the outset, Applicant notes that the Examiner only discusses claim 1 with reference to cooling tissue to prevent metabolism of the pre-photosensitizing agent in epithelial tissue surrounding the targeted treatment site while allowing the pre-photosensitizing agent to metabolize into a photosensitizing agent in tissue at the targeted treatment site. Claim 4 refers to cooling, but claim 4 ultimately depends from broader independent claim 1. Thus, even though Applicant's argument below regarding claim 1 refers to cooling tissue to prevent metabolism, it is understood that claim 1 is not limited to cooling tissue to prevent metabolism (as exemplified by dependent claim 23).

Tankovich discloses a number of methods for removing hair. In rejecting claim 1, the Examiner refers to elements included in two of Tankovich's methods, Method No. 8: Sunlight-Assisted Hair Removal (Col. 37, line 64 to Col. 40, line 17) and Method No. 22: Hair Removal by Combination of Long Pulse Laser With Skin Cooling (Col. 63, line 15 to Col. 67, line 27). These two methods are unrelated, do not refer to each other, and are separated by over twenty columns of text discussing other hair removal methods.

A person skilled in the art reading Tankovich has no reason to pick and choose elements from these disparate methods without using knowledge acquired from the present application. As such, combining these elements from Tankovich is based on impermissible hindsight reasoning and thus cannot make claim 1 obvious.

Tankovich's Method Nos. 8 and 22 would have to be combined to disclose the elements of claim 1 because only Method No. 8 refers to application of a chemical, e.g., ALA, while only Method No. 22 refers to cooling of the skin surface. Method Nos. 8 and 22 would not and could not be combined by a person skilled in the art because their combination would not lead to desired and predicted results. In order to cool the skin surface in Method No. 8 so as to prevent metabolism, the skin surface would have to be cooled throughout its exposure to sunlight, a time typically on the order of hours. In contrast, skin is cooled in Method No. 22 for "about 1 to 5 seconds" (Col. 65, lines 40-46) so as to maintain adequate skin surface cooling for the duration of irradiation with a laser pulse, "a period of about 0.1 second." (Col. 66, lines 13-22.) A person skilled in the art would not combine the cooling in Method No. 22 with the sunlight exposure in Method No. 8 at least because skin cooling has to occur throughout irradiation, and the time differences between Method Nos. 8 and 22 differ by an order of magnitude of at least 12,000 (20 minutes of sunlight exposure vs. 0.1 seconds of a laser pulse). Such prolonged skin cooling in Method No. 8 would cool not just on the skin surface but below the skin surface so as to prevent any effective treatment using ALA. Furthermore, such prolonged skin exposure to cold would likely induce dangerous hypothermic conditions since the skin would have to be continuously cooled for at least 20 minutes and more typically for about 3-4 hours of sunlight exposure.

Accordingly, claim 1, as well as claims 2-19 and 22, which depend therefrom, therefore distinguish over Tankovich and Klatz, either taken alone or together, and represent allowable subject matter.

Claims 20-21

The Examiner rejects claims 20-21 pursuant to 35 U.S.C. §103(a) as being obvious over Tankovich and further in view of U.S. Patent No. 5,955,490 ("Kennedy"). Applicant respectfully disagrees.

At the outset, Applicant notes that the Examiner refers to Klatz in the text discussing this rejection (see, e.g., paragraph 28 on page 11 of the Office Action) and seems to be rejecting claims 20-21 as obvious over Tankovich in view of Klatz and further in view of Kennedy. Applicant will interpret dependent claims 20-21 as being rejected as obvious over Tankovich in view of Klatz and further in view of Kennedy.

At least for the reasons discussed above, Tankovich and Klatz do not make obvious independent claim 1. Kennedy is relied on only for dependent claim features, namely that the targeted treatment site can include malignant cells or sebaceous glands, and does not remedy the deficiencies of Tankovich and Klatz. Accordingly, claim 20-21 distinguish over Tankovich, Klatz, and Kennedy, either taken alone or together, and are allowable at least because they depend from an allowable base claim.

Claims 23-34

The Examiner rejects claims 23-34 pursuant to 35 U.S.C. §103(a) as being obvious over Tankovich and further in view of Kennedy and U.S. Patent No. 5,955,490 ("Hess"). Applicant respectfully disagrees.

At the outset, Applicant notes that the Examiner refers to Klatz in the text discussing this rejection (see, e.g., paragraph 37 on page 15 of the Office Action). Applicant will interpret dependent claims 23-34 as being rejected as obvious over Tankovich in view of Klatz and further in view of Kennedy and Hess.

At least for the reasons discussed above, Tankovich, Klatz, and Kennedy do not make obvious independent claim 1. Hess is relied on only for dependent claim features, namely that succinylacetone is an inhibitor of ALA, and does not remedy the deficiencies of Tankovich and Klatz. Accordingly, claim 23-24 distinguish over Tankovich, Klatz, and Kennedy, either taken alone or together, and are allowable at least because they depend from an allowable base claim.

CONCLUSION


Applicant submits that all pending claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant's amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22727-110.

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Respectfully submitted,

By 
Charlton Shen
Registration No.: 54,442
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2000
(617) 310-9000 (Fax)
Attorney for Applicant